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10/006,775	12/10/2001	Stephen Mastorides	D6350A	2032

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EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 09/08/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,775

Applicant(s)

MASTORIDES ET AL.

Examiner

Alexander H. Spiegler

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support for the instant application because the instant application was filed later than 12 months after the date on which the provisional application was filed. (See 35 USC § 119(e))

The provisional application was filed on November 30, 2000, whereas the instant application was filed on December 10, 2001 (See dismissal of petition mailed on July 17, 2002); thus the instant application was filed more than 12 months after the filing date of the provisional application. Accordingly, Applicants do not receive the benefit of the provisional application filed on November 30, 2000.

Drawings

2. New corrected drawings are required in this application because Figures 4, 6 and 7 are unclear as to what is being depicted. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because the application claims benefit of priority of provisional U.S. Serial Number 60/250,084, however, as discussed above, the instant application

Art Unit: 1637

does not receive the benefit of this provisional. Accordingly, Applications should amend the specification in accordance with the correct status of the application.

4. Claim 3 is objected to over the recitation of "said said", which appears to be a typographical error. Applicants should delete one of the recitations of "said".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-12 are rejected under 35 U.S.C. 102(a) as being anticipated by Hoos et al.

(Laboratory Investigation (October 2001) 81(10): 1331-1338).

Hoos et al. teaches a cryoarray device comprising:

a mold plate having an upper and a lower surface;

mold alignment pins, said mold alignment pins perpendicularly attached to the lower surface of said mold plate;

an ejector plate having an upper surface and a lower surface, said plate comprising holes between said upper surface and said lower surface;

ejector pins, said ejector pins comprising ejector thumb pads attached to an upper surface of said pins, said ejector pins connecting said mold plate and said ejector plate;

and cryoarray pins, said cryoarray pins equal in number to said holes in said ejector plate and aligned with said holes in said ejector plate. (See Figs. 3-4 and pgs. 1335-1336, for example)

Hoos et al. also teaches the cryoarray device,

Art Unit: 1637

wherein said mold alignment pins direct the placement of said device into a tissue mold;
wherein said cryoarray pins connect operably to the lower surface of said mold plate and are capable of passing through said holes in said ejector plate;

wherein said ejector pins are capable of lowering and of raising said ejector plate over said cryoarray pins;

further comprising: ejector springs, each of said springs surrounding an outer surface of each of said ejector pins and operably located between said upper surface of said mold plate and said lower surface of one of said ejector thumb pads. (See Figs. 3-4 and pgs. 1335-1336, for example)

Hoos et al. also teaches a cryoarray system for forming an array for frozen tissue, comprising: a tissue mold; an embedding medium, said embedding medium filling said tissue mold, said embedding medium capable of being frozen therein, said frozen embedding medium forming a recipient tissue block; and the cryoarray device above, said device placed in said tissue mold with said embedding medium, but prior to freezing said embedding medium; wherein freezing said embedding medium around said cryoarray pins of the device above creates grid holes into said recipient block upon separation of said cryoarray device from said recipient block thereby forming an array in said recipient block for frozen tissue. (See Abstract, Figs. 3-4 and pgs. 1332 and 1335-1336, for example)

Hoos et al. also teaches the cryoarray device,

wherein said embedding medium is O.C.T. TM compound;

wherein said embedding material is frozen at a temperature of about -20.degree. C. to about -80.degree. C; and

Art Unit: 1637

wherein said recipient block is separated from said cryoarray device by depressing said ejector pins to lower said ejector plate over said cryoarray pins. (See Figs. 3-4 and pgs. 1335-1336, for example)

Hoos et al. also teaches a method for preparing tissue for assays, comprising the steps of: selecting at least one frozen tissue core from a donor block; inserting each of said at least one frozen core into said grid holes of said recipient block of the cryoarray system above; cutting sections from said array; and assaying said sections.

Hoos et al. also teach the method,

wherein said tissue is from about 1.0 mm to about 3.0 mm in diameter;

wherein said tissue is from about 2.5 mm to about 3.0 mm in diameter;

wherein said tissue assay is selected from the group consisting of morphologic evaluation, in situ hybridization, immunohistochemistry, in situ polymerase chain reaction and fluorescence in situ hybridization. (See Abstract, Figs. 3-4 and pgs. 1332 and 1335-1336, for example)

7. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinkel et al. (USPN 5,690,894).

Pinkel et al. teaches a cryoarray device comprising:

a mold plate having an upper and a lower surface;

mold alignment pins, said mold alignment pins perpendicularly attached to the lower surface of said mold plate;

an ejector plate having an upper surface and a lower surface, said plate comprising holes between said upper surface and said lower surface;

Art Unit: 1637

ejector pins, said ejector pins comprising ejector thumb pads attached to an upper surface of said pins, said ejector pins connecting said mold plate and said ejector plate;

and cryoarray pins, said cryoarray pins equal in number to said holes in said ejector plate and aligned with said holes in said ejector plate. (See Fig. 4 and cols. 5-12, for example)

Pinkel et al. teaches a cryoarray device comprising,
wherein said mold alignment pins direct the placement of said device into a tissue mold;
wherein said cryoarray pins connect operably to the lower surface of said mold plate and are capable of passing through said holes in said ejector plate;

wherein said ejector pins are capable of lowering and of raising said ejector plate over said cryoarray pins. (See Fig. 4 and cols. 5-12, for example)

It is noted, the recitations of “cryoarray device”, “mold alignment pins” and “cryoarray pins” do not have any structural limitations associated with them, and therefore, are not given any patentable weight. Similarly, Claim 2 is drawn to an intended use of the mold alignment pins, and therefore, is also not given any patentable weight.

8. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Fleming (USPN 4,654,989).

Fleming et al. teaches a cryoarray device comprising:

a mold plate having an upper and a lower surface;

mold alignment pins, said mold alignment pins perpendicularly attached to the lower surface of said mold plate;

an ejector plate having an upper surface and a lower surface, said plate comprising holes between said upper surface and said lower surface;

Art Unit: 1637

ejector pins, said ejector pins comprising ejector thumb pads attached to an upper surface of said pins, said ejector pins connecting said mold plate and said ejector plate;

and cryoarray pins, said cryoarray pins equal in number to said holes in said ejector plate and aligned with said holes in said ejector plate. (See Figs. 1-5 and cols. 2-3, for example)

Fleming et al. also teaches the cryoarray device, wherein said mold alignment pins direct the placement of said device into a tissue mold; wherein said cryoarray pins connect operably to the lower surface of said mold plate and are capable of passing through said holes in said ejector plate;

wherein said ejector pins are capable of lowering and of raising said ejector plate over said cryoarray pins. (See Figs. 1-5 and cols. 2-3, for example)

It is noted, the recitations of "cryoarray device", "mold alignment pins" and "cryoarray pins" do not have any structural limitations associated with them, and therefore, are not given any patentable weight. Similarly, Claim 2 is drawn to an intended use of the mold alignment pins, and therefore, is also not given any patentable weight.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fleming (USPN 4,654,989) as applied to claims 1-3 above, and further in view of Vollom (USPN 6,298,587).

Art Unit: 1637

The teachings of Fleming are presented above. Specifically, Fleming teaches the claimed device, but does not teach said device comprising ejector pins that are capable of lowering and of raising the ejector plate over the cryoarray pins.

However, Vollom teaches the lowering and raising the ejector place over the cryoarray pins (see cols. 1-2). Specifically, Vollom expressly incorporates the teachings of Fleming (see col. 1), and teaches that a moving ejector plate is advantageous for allowing the pin screen to be reset while in a vertical position.

In view of the teachings of Vollom, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Fleming so as to have a moveable ejector plate, in order to have achieved the benefit of allowing the pin screen to be reset while in a vertical position.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Leighton USPN 6,103,518

Muraca USPN 6,534,307

Kononen et al. Nature Medicine (1998) 4(7) : 844-847

Bubendorf et al. Cancer Research (1999) 59 : 803-806

12. No Claims are allowable.

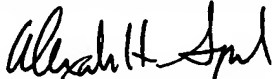
Art Unit: 1637

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the primary examiner in charge of the prosecution of this case, Carla Myers, can be reached at (703) 308-2199. If attempts to reach Carla Myers are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Alexander H. Spiegler
September 4, 2003



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